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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,642	11/12/2003	Gloria C. Li	1747 / 55672-AA-PCT-US/JP	8975
57530	7590	02/04/2009	EXAMINER	
COOPER & DUNHAM LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112			ZARA, JANE J	
			ART UNIT	PAPER NUMBER
			1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,642

Applicant(s)

LI ET AL.

Examiner

Jane Zara

Art Unit

1635

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-17-09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-33 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-33 and 35-38 is/are allowed.
- 6) ☒ Claim(s) 27, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This Office action is in response to the communication filed 10-17-09.

Claims 27-33, 35-40 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves et al (J. Biol. Chem., Vol. 264(9): 5047-5052, 1989) and Milner et al (Nature Biotech. 15: 537-541, 1997), the combination in view of Taniguchi et al (Genomics 35: 129-135, 1996), Reed et al (Proc. Natl. Acad. Sci., Vol. 87, pages 3660-3664, 1990) and Au-Young et al (USPN 5,773,580) insofar as the claims are drawn to compositions and methods for increasing a target cell's sensitivity to DNA damaging agents in vitro or upon direct administration comprising the administration of an

antisense oligonucleotide, optionally in an adenoviral expression vector comprising a heat shock promoter, that specifically hybridizes with a nucleic acid encoding a DNA dependent protein kinase subunit (Ku70), which antisense inhibits the expression of the target Ku70 subunit for the reasons of record set forth in the Office action mailed 2-7-08.

Applicant's arguments filed 10-17-08 have been fully considered but they are not persuasive. Applicant argues that the references cited do not render the instant invention obvious because Reeves does not teach an antisense nucleic acid which has the sequence of a human Ku70 cDNA in the antisense orientation, and, according to Applicant, Reed is improperly relied upon because the teaching of a full length antisense sequence to a different target gene is not predictive of an antisense having the sequence of a human Ku70 cDNA. Applicant also argues that Milner discusses the need for testing the efficacy of antisense to inhibit their respective target genes, thus indicating the efficacy of an antisense must be tested and is therefore not predictable.

Contrary to Applicant's assertions, the instant invention would have been obvious in light of the teachings of the prior art of record. The disclosure of the target Ku70 polynucleotide sequence by Reeves, combined with the routine experimentation taught previously by Milner for designing and testing the ability of antisense to a known target gene to inhibit the expression of that target gene in vitro, and the routine experimentation taught previously by Reed for subcloning and expressing a full length antisense in an appropriate expression vector, which antisense can then be routinely tested for target gene inhibition relying on the methods of Milner, indeed collectively render the instant invention obvious. Furthermore, the teachings of Reeves concerning

the binding of Ku70 to the ends of double stranded DNA in a complex with Ku80, and the well known teachings of Takiguchi, of the role of mouse and human DNA-PK in DNA repair, and the teachings of all of the subunits of DNA-PK - Ku70, Ku80 and DNA-PK catalytic subunit - and their combined role in DNA repair, provide the motivation to inhibit the expression of the various DNA-PK subunits using antisense in vitro in order to study the affect of DNA-PK on cell repair and other cellular functions, and in order to begin screening for therapeutic candidates for aberrant conditions stemming from DNA repair malfunction and the predictable increase in a cell's sensitivity to DNA damaging agents with loss of DNA-PK function.

The extrapolation from in vitro target gene inhibition to in vivo efficacy is an unpredictable one, but, despite the fact that various antisense molecules are to be tested empirically in vitro for their ability to inhibit expression of target gene inhibition, the ability to test such antisense candidates for such target gene inhibition in vitro only requires routine experimentation, including full length antisense subcloned into well known expression vectors, and targeting a gene of previously determined sequence, such as Ku70.

For these reasons, the instant rejection for obviousness I maintained.

Double Patenting

Claims 27, 39 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 15,

16 and 18-22 of copending Application No. 09/750,410 for the reasons of record set forth in the Office actions mailed 4-13-06, 1-11-07, and 2-7-08.

Nor arguments were made addressing this rejection.

Allowable Subject Matter

Claims 28-33, and 35-38 appear free of the prior art searched and of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original

signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-30-09

/Jane Zara/

Primary Examiner, Art Unit 1635